UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/484,928	06/07/1995	GARY K. MICHELSON	P-12509	5055

7590 04/23/2002

MARTIN & FERRARO, LLP
14500 AVION PARKWAY, SUITE 300
CHANTILLY, VA 20151-1101

EXAMINER
REIP, DAVID OWEN

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/484,928	Applicant(s) MICHELSON, GARY K.	
	Examiner David O. Reip	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,28-51,53-75,77-82,86-96,98,101-132 and 135-172* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26 and 28-51* is/are allowed.

6)☒ Claim(s) *1-25,53-75,77-82,86-96,98,101-132 and 135-172* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *05 December 2000* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The current status of all related applications mentioned at page 2, first paragraph, must be updated. See also page 9, 2nd full paragraph and page 11, 2nd full paragraph.

Preliminary to addressing the substance of the claims, it should be noted that in the original presentation of claims 1-136, there was no claim 46. Additionally, in the presentation of new claims 137-167 by the amendment of March 27, 1997, there was no claim 152. Therefore, claim numbering clearly does not comply with the applicable rules. However, for purposes of this action and expediting prosecution as to the merits, and in order to reduce the chance of further confusion, all claims will be addressed as they are currently numbered in the application. Response to this action must include appropriate measures to bring all claim numbering into compliance with the applicable rules.

Specification

Objection is made to the specification under 37 CFR 1.75(d)(1) as failing to provide proper antecedent terminology for certain words, phrases, and features presented in the claims. For example, claims 5, 30, 55, and 101 require the insertion end to be larger than the trailing end. This is nowhere addressed or alluded to in the

description. Additionally, the subject matter of claim 28 wherein the body is part cylindrical as well as part frusto-conical is not described in the specification.

Drawings

Objection is made to the drawing under 37 CFR 1.83(a) as failing to illustrate the claimed subject matter of claims 144, 151, 16, 41, 66, 88, 114, and 28. There is no illustration of the knurling or of the part cylindrical and part frusto-conical form.

Referring to the specification and drawing, the following reference numeral and related deficiencies are noted:

page 9, third line from the bottom, "222'" is not in Fig. 3A;

page 10, line 7, "body 220'" should be -- body 222'--;

page 10, line 16, "240'" should be -- 240"--;

page 10, lines 21, 24, and 28, "220'" should be -- 220"--;

page 10, line 24, "L4" should be -- L5 --;

page 10, line 27, "240'" should be -- 240" --;

page 11, line 11, "339" is not in the drawing;

page 11, lines 16, 19, and 21, "320a" is not in Figs. 9 and 10;

page 11, lines 18 and 21, "338" is not in Figs. 9 and 10;

page 11, line 26, "320" should be -- 320a --.

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 163-167 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement in that the original description does not even allude to the specific dimensions set forth in these claims. The substance of these claims is clearly new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5, 17-20; 22, 24, and 25 are rejected under 35 U.S.C. 102(e) as anticipated by Godefroy, et al. (5,683,463). Claim 1 is of such breadth that it can, without difficulty, be read on this reference. Note the illustration of the frusto-conical shape (column 1, line 66, et seq.) and the bone engaging means 13, 14, 16 (column 2, lines 58-65 and column 3, lines 3-5).

Regarding claim 2, see column 1, lines 47-50 and column 3, lines 11-18.

Regarding claim 5, the discussion bridging columns 3 and 4 of Godefroy, et al. coupled with Fig. 3 shows that the insertion end is in fact larger than the trailing end.

Regarding claims 17, 18, 19, and 20, the internal chamber, its means for accessing, and the plurality of openings are clearly shown in the Godefroy, et al. drawing.

Regarding claim 22, see column 3, lines 41-43 of Godefroy, et al.

Regarding claim 24, the capability expressed in this claim is present in Godefroy, et al. by reason of the truncated sides shown in Fig. 3. Mere capability by the reference structure of performing the recited function is sufficient for anticipation.

Regarding claim 25, see Fig. 3 of Godefroy, et al.

Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as anticipated by Stuhmer (4,245,359). Under the law of anticipation, it is necessary only that the claim in question "read on" the reference. As to functions recited, it is necessary only that the prior art be "capable of" performing the intended function. That being the case, claim 1 will read on Stuhmer and is therefore anticipated. The bone engaging means 6 of

Stuhmer is substantially frusto-conical (column 2, lines 59-62 and Fig. 1). The element of Stuhmer is fully capable of being implanted into the spine and contacting or engaging adjacent vertebral bodies. The nominal designation of the implant in the preamble does not give life and meaning to the claim.

Regarding claim 3, the body of element 3 in Stuhmer is cylindrical (column 2, lines 31-32).

Regarding claim 4, the trailing end at the top of Fig. 1 is larger than the insertion end at the bottom.

Claims 53, 55, 67-70, 72, 74, and 75 are rejected under 35 U.S.C. 102(e) as anticipated by Godefroy, et al. for essentially the same reasons given in the rejection of claim 1 over this reference. Claim 53 is of such breadth that it can, without difficulty, be read on this reference. Note the illustration of the frusto-conical shape (column 1, line 66, et seq.) and the bone engaging means 13, 14, 16 (column 2, lines 58-65).

Regarding claim 55, the discussion bridging columns 3 and 4 of Godefroy, et al. coupled with Fig. 3 shows that the insertion end is in fact larger than the trailing end.

Regarding claims 67-70, the internal chamber, its means for accessing, and the plurality of openings are clearly shown in the Godefroy, et al. drawing.

Regarding claim 72, see column 3, lines 41-43 of Godefroy, et al.

Regarding claim 74, the capability expressed in this claim is present in Godefroy, et al. by reason of the truncated sides shown in Fig. 3. Mere capability by the reference structure of performing the recited function is sufficient for anticipation.

Regarding claim 75, see Fig. 3 of Godefroy, et al.

Claims 98, 101, 102, 115-118, 120, 122, 123, 154, and 159 are rejected under 35 U.S.C. 102(e) as anticipated by Godefroy, et al. Godefroy, et al. discloses a substantially frusto-conical body (drawing; column 1, lines 66-67) for the purpose of maintaining angulation of adjacent vertebral bodies (column 1, lines 47-50). Regarding claim 101, the discussion bridging columns 3 and 4 of Godefroy, et al. coupled with Fig. 3 shows that the insertion end is in fact larger than the trailing end. Regarding claim 102, the implant in Godefroy, et al. is tapered in its entirety.

Claims 124, 125, 130, 155, and 160 are rejected under 35 U.S.C. 102(e) as anticipated by Godefroy, et al. The implant of Godefroy, et al. clearly has bone engaging means 13, 14, 16 with an outer locus that is substantially frusto-conical along at least a portion of the length of the implant nearer the trailing end than the insertion end no matter which end is considered to be the trailing or insertion end.

Claims 124 and 126 are rejected under 35 U.S.C. 102(b) as anticipated by Stuhmer for the same reasons given above in the rejection of claim 1 over this reference.

Claims 137, 138, 156, and 161 are rejected under 35 U.S.C. 102(e) as anticipated by Godefroy, et al. clearly showing the distance between arcuate portions

increasing from a first end at the left of Fig. 1 to a second end at the right of Fig. 1. Godefroy, et al. shows bone engaging means 13, 14, and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 7, 9, 10, 14-16, and 23 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Brantigan (4,878,915). Godefroy, et al. discloses the implant claimed including the recited frusto-conical configuration, but does not set forth the various claimed surface details. However, the numerous surface configurations suggested by Brantigan provide ample evidence to support a conclusion of obviousness in providing the Godefroy, et al. implant with these various surface configurations for the purpose of enhancing bone ingrowth and fusion. In Brantigan, see the knurlings in Fig. 6, the ratchetings in Fig. 8, the pits (corresponding to "porous",

"wells", and openings as recited) in Fig. 7, and the surface roughening in Figs. 10 and 11.

Claim 8 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. and in view of the taking of official notice of the indisputable fact that the use of at least part bioabsorbable material in various implants is well known in the implant art generally. It would have been obvious to form at least a portion of the implant of Godefroy, et al. to be bioabsorbable in order to allow the point of surgery to recover, as much as feasible, to its natural state.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Van Kampen. Godefroy, et al. does not disclose the post arrangement disclosed, but Van Kampen clearly suggest such an arrangement for promoting ingrowth and mechanical interlocking of tissue in various implant environments. It would have been obvious for one having ordinary skill in this art to have employed this arrangement in Godefroy, et al. to insure proper tissue ingrowth and a strong bond with the vertebral bodies.

Claim 13 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of ordinary skill in this art to employ such mesh-like

material in the implant of Godefroy, et al. in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claim 21 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Kuslich, et al. While Godefroy, et al. does not specifically suggest a means to close the access opening for the chamber, Kuslich, et al. clearly teaches the use of such a means (18, 20) in a like environment. It would have been obvious to provide such a means in Godefroy, et al. to ensure containment of the bone fragments which may be inserted in the chamber.

Claim 54 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Pavlov, et al. (5,906,616). In Godefroy, et al., it is the insertion end that is larger than the trailing end rather than the converse as claimed here. However, Pavlov, et al. gives ample evidence that both options are equally well known. Compare Figs. 7-9 with Figs. 21-23 of Pavlov, et al. It would have been readily obvious to employ the Godefroy, et al. implant in both an insertion mode where the leading end is smaller, and an insertion mode where the trailing end is smaller, depending on the particular portion of the spine in which the implant is used and whether a conventional anterior or posterior approach is used, in order to obtain the benefits of the Godefroy implant regardless of the method of implanting it.

Claims 56, 57, 59, 60, 64-66, and 73 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Brantigan (4,878,915). Godefroy, et al. discloses the implant claimed including the recited frusto-conical configuration, but does not set forth the various claimed surface details. However, the numerous surface configurations suggested by Brantigan provide ample evidence to support a conclusion of obviousness in providing the Godefroy, et al. implant with these various surface configurations for the purpose of enhancing bone ingrowth and fusion. In Brantigan, see the knurlings in Fig. 6, the ratchetings in Fig. 8, the pits (corresponding to "porous", "wells", and openings as recited) in Fig. 7, and the surface roughening in Figs. 10 and 11.

Claim 58 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. and in view of the taking of official notice of the indisputable fact that the use of at least part bioabsorbable material in various implants is well known in the implant art generally. It would have been obvious to form at least a portion of the implant of Godefroy, et al. to be bioabsorbable in order to allow the point of surgery to recover, as much as feasible, to its natural state.

Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Van Kampen. Godefroy, et al. does not disclose the post arrangement disclosed, but Van Kampen clearly suggests such an arrangement for promoting ingrowth and mechanical interlocking of tissue in various implant

environments. It would have been obvious for one having ordinary skill in this art to have employed this arrangement in Godefroy, et al. to insure proper tissue ingrowth and a strong bond with the vertebral bodies.

Claim 63 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of ordinary skill in this art to employ such mesh-like material in the implant of Godefroy, et al. in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claim 71 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Kuslich, et al. While Godefroy, et al. does not specifically suggest a means to close the access opening for the chamber, Kuslich, et al. clearly teaches the use of such a means (18, 20) in a like environment. It would have been obvious to provide such a means in Godefroy, et al. to ensure containment of the bone fragments which may be inserted in the chamber.

Claims 77, 78, 79, 81, 82, 86-88, 94, 95, 158, and 163 are rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan (4,878,915), for example, in view of Van Kampen. Brantigan gives ample evidence of a non-threaded interbody spinal fusion implant (title; line 3 of the abstract; column 7, line 1, for example) that is cylindrical

(column 5, line 10; column 6, line 9; Figs. 6 and 8-11, for example). Brantigan does not disclose an outer surface with a plurality of posts having heads wider than the stems. Rather, Brantigan suggests various other surface configurations for facilitating bone ingrowth, and specifically suggests even further configurations not discussed (column 6, lines 59-63). Van Kampen specifically suggests a post arrangement on implants generally (column 2, line 59, et seq.) with heads wider than the stems (Figs. 4-5; paragraph bridging pages 5-6; paragraph bridging pages 7-8). It would have been obvious to a person having ordinary skill in this art to have provided such a post arrangement in Brantigan for the purpose of insuring mechanical interlocking of tissue as explicitly suggested by Van Kampen (column 1, lien 46; column 4, lines 52-53; column 5, line 61, for example). Regarding claim 163, the dimensions recited are within the reasonable limits of the size that would be expected by those having ordinary skill in this art given the restraints inherent in the normal human vertebral body. Thus, it would have been obvious to select a size within the limits recited in this claim.

Claims 89-92, 96, and 153 are rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Van Kampen as set forth in the rejection of claims 77 and 78 above, and further in view of Godefroy, et al. While Brantigan lacks a chamber and its appurtenances as claimed, such structure is shown in Godefroy, et al. in a fusion implant, as is the truncated side surfaces. It would have been obvious to provide the chamber in Brantigan in order to receive fusion material and to provide the truncated

side surfaces to both reduce the volume of the implant and to enable dual implants to placed in close proximity while taking up less lateral space.

Claim 93 is rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Van Kampen and Godefroy, et al. as set forth in the preceding paragraph, and further in view of Kuslich, et al. While Godefroy, et al. does not specifically suggest a means to close the access opening for the chamber, Kuslich, et al. clearly teaches the use of such a means (18, 20) in a like environment. It would have been obvious to provide such a means in Brantigan, as modified by the teachings of Godefroy, et al., to ensure containment of the bone fragments which may be inserted in the chamber.

Claim 80 is rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Van Kampen and further in view of the taking of official notice of the indisputable fact that the use of at least part bioabsorbable material in various implants is well known in the implant art generally. It would have been obvious to form at least a portion of the implant of Brantigan to be bioabsorbable in order to allow the point of surgery to recover, as much as feasible, to its natural state.

Claim 103 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Pavlov, et al. (5,906,616). In Godefroy, et al., it is the insertion end that is larger than the trailing end rather than the converse as claimed here. However, Pavlov, et al. gives ample evidence that both options are equally well known. Compare Figs. 7-

9 with Figs. 21-23 of Pavlov, et al. It would have been readily obvious to employ the Godefroy, et al. implant in both an insertion mode where the leading end is smaller, and an insertion mode where the trailing end is smaller, depending on the particular portion of the spine in which the implant is used and whether a conventional anterior or posterior approach is used, in order to obtain the benefits of the Godefroy implant regardless of the method of implanting it.

Claims 104, 105, 107, 108, 112-114, and 121 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Brantigan (4,878,915). Godefroy, et al. discloses the implant claimed including the recited frusto-conical configuration, but does not set forth the various claimed surface details. However, the numerous surface configurations suggested by Brantigan provide ample evidence to support a conclusion of obviousness in providing the Godefroy, et al. implant with these various surface configurations for the purpose of enhancing bone ingrowth and fusion. In Brantigan, see the knurlings in Fig. 6, the ratchetings in Fig. 8, the pits (corresponding to "porous", "wells", and openings as recited) in Fig. 7, and the surface roughening in Figs. 10 and 11.

Claim 106 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. and in view of the taking of official notice of the indisputable fact that the use of at least part bioabsorbable material in various implants is well known in the implant art generally. It would have been obvious to form at least a portion of the implant of

Godefroy, et al. to be bioabsorbable in order to allow the point of surgery to recover, as much as feasible, to its natural state.

Claims 109 and 110 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Van Kampen. Godefroy, et al. does not disclose the post arrangement disclosed, but Van Kampen clearly suggests such an arrangement for promoting ingrowth and mechanical interlocking of tissue in various implant environments. It would have been obvious for one having ordinary skill in this art to have employed this arrangement in Godefroy, et al. to insure proper tissue ingrowth and a strong bond with the vertebral bodies.

Claim 111 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of ordinary skill in this art to employ such mesh-like material in the implant of Godefroy, et al. in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claim 119 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Kuslich, et al. While Godefroy, et al. does not specifically suggest a means to close the access opening for the chamber, Kuslich, et al. clearly teaches the use of such a means (18, 20) in a like environment. It would have been obvious to

provide such a means in Godefroy, et al. to ensure containment of the bone fragments which may be inserted in the chamber.

Claim 164 is rejected under 35 U.S.C. 103 as unpatentable over Godefroy, et al. for the reasons given in the rejection of claim 98 above, further in view of the obvious fact that the dimensions recited are within the reasonable limits of the size that would be expected by those having ordinary skill in this art given the restraints inherent in the normal human vertebral body. Thus, it would have been obvious to select a size within the limits recited in this claim.

Claim 127 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Van Kampen. Godefroy, et al. does not disclose the post arrangement disclosed, but Van Kampen clearly suggests such an arrangement for promoting ingrowth and mechanical interlocking of tissue in various implant environments. It would have been obvious for one having ordinary skill in this art to have employed this arrangement in Godefroy, et al. to insure proper tissue ingrowth and a strong bond with the vertebral bodies.

Claim 128 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of ordinary skill in this art to employ such mesh-like

material in the implant of Godefroy, et al. in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claim 129 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Brantigan. Arguably, the elements 13, 14, 16 of Godefroy, et al are surface roughening, but to the extent it is deemed otherwise, Brantigan explicitly teaches the use of surface roughening for bone ingrowth. It would have been obvious to employ surface roughening in Godefroy, et al. for that same purpose.

Claim 165 is rejected under 35 U.S.C. 103 as unpatentable over Godefroy, et al. for the reasons given in the rejection of claim 124 above, further in view of the obvious fact that the dimensions recited are within the reasonable limits of the size that would be expected by those having ordinary skill in this art given the restraints inherent in the normal human vertebral body. Thus, it would have been obvious to select a size within the limits recited in this claim.

Claims 131, 132, 135, and 168 are rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Ducheyne. Brantigan discloses a spinal fusion implant having a body being formed of various surface irregularity configurations to enhance fusion, but does not explicitly disclose a mesh-like material. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of

ordinary skill in this art to follow Brantigan's explicit suggestion at column 6, line 59-63 to consider other types of rough or irregular surfaces, and employ mesh-like material to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claim 136 is rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Ducheyne for the same reasons given in the rejection above of claim 131, and further in view of Godefroy, et al. While Brantigan does not show truncated sides, such a feature is taught clearly in Godefroy, et al. It would have been obvious to provide truncated side surfaces in Brantigan to both reduce the volume of the implant and to enable dual implants to placed in close proximity while taking up less lateral space.

Claim 139 and 140 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Van Kampen. Godefroy, et al. does not disclose the post arrangement disclosed, but Van Kampen clearly suggests such an arrangement for promoting ingrowth and mechanical interlocking of tissue in various implant environments. It would have been obvious for one having ordinary skill in this art to have employed this arrangement in Godefroy, et al. to insure proper tissue ingrowth and a strong bond with the vertebral bodies.

Claim 141 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example).

It would have been obvious to one of ordinary skill in this art to employ such mesh-like material in the implant of Godefroy, et al. in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claims 142-144 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Brantigan. While Godefroy, et al. does not show the particular surface features recited, each is clearly disclosed by Brantigan in a similar environment for the purpose of tissue ingrowth and fusion. It would have been obvious to provide Godefroy, et al. with such surface features in order to promote tissue ingrowth and fusion.

Claim 166 is rejected under 35 U.S.C. 103 as unpatentable over Godefroy, et al. for the reasons given in the rejection of claim 137 above, further in view of the obvious fact that the dimensions recited are within the reasonable limits of the size that would be expected by those having ordinary skill in this art given the restraints inherent in the normal human vertebral body. Thus, it would have been obvious to select a size within the limits recited in this claim.

Claims 145, 157, and 162 are rejected under 35 U.S.C. 102(e) as anticipated by Godefroy, et al. The bone engaging means 13, 14, 16 of Godefroy, et al. have arcuate portions wherein the distance between arcuate portions increases from a first end to a second end.

Claims 146 and 147 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Van Kampen. Godefroy, et al. does not disclose the post arrangement disclosed, but Van Kampen clearly suggests such an arrangement for promoting ingrowth and mechanical interlocking of tissue in various implant environments. It would have been obvious for one having ordinary skill in this art to have employed this arrangement in Godefroy, et al. to insure proper tissue ingrowth and a strong bond with the vertebral bodies.

Claim 148 is rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Ducheyne. Ducheyne teaches the use of mesh-like material for a broad range of implants in order to enhance bone growth (column 9, lines 48-54, for example). It would have been obvious to one of ordinary skill in this art to employ such mesh-like material in the implant of Godefroy, et al. in order to enhance bone ingrowth as explicitly suggested by Ducheyne.

Claims 149-151 are rejected under 35 U.S.C. 103(a) as unpatentable over Godefroy, et al. in view of Brantigan. While Godefroy, et al. does not show the particular surface features recited, each is clearly disclosed by Brantigan in a similar environment for the purpose of tissue ingrowth and fusion. It would have been obvious to provide Godefroy, et al. with such surface features in order to promote tissue ingrowth and fusion.

Claim 167 is rejected under 35 U.S.C. 103 as unpatentable over Godefroy, et al. for the reasons given in the rejection of claim 145 above, further in view of the obvious fact that the dimensions recited are within the reasonable limits of the size that would be expected by those having ordinary skill in this art given the restraints inherent in the normal human vertebral body. Thus, it would have been obvious to select a size within the limits recited in this claim.

Claims 169-171 are rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Hirabayashi, et al. Brantigan discloses an implant body with various surface configurations to promote fusion and suggests others may be used (column 6, lines 59-63). Brantigan does not specifically disclose "cancellous material." However, it should be noted that the embodiment in Fig. 7 and column 6, lines 24-29 of Brantigan is arguably "cancellous material" by the broad definition of that term. At any rate, Hirabayashi, et al. discloses in Fig. 3 a net-like working structure to promote bone ingrowth in various implant procedures (column 3, line 15; column 4, line 10; column 12, lines 46-49). It would have been obvious to one having ordinary skill in this art to have followed Brantigan's explicit suggestion to use other types of rough or irregular surfaces and employ cancellous material as explicitly taught by Hirabayashi, et al. in order to promote rigid bonding to the implant.

Claim 172 is rejected under 35 U.S.C. 103(a) as unpatentable over Brantigan in view of Hirabayashi, et al. for the reasons given in the preceding paragraph, further in view of Godefroy. While Brantigan does not show truncated sides, such a feature is taught clearly in Godefroy, et al. It would have been obvious to provide truncated side surfaces in Brantigan to both reduce the volume of the implant and to enable dual implants to placed in close proximity while taking up less lateral space.

Allowable Subject Matter

Claim 26 and each of its dependent claims 28-45 and 47-51 (there being no claim 46) are allowable because claim 26, clearly directed toward the embodiment set forth in Fig. 3A, specifically requires that the body portion of the implant have a substantially frusto-conical configuration while the locus of the bone engaging means forms a substantially cylindrical configuration.

Conclusion

In the foregoing rejections, where features have been addressed directly for dependent claims under a given independent claim, but not addressed directly for a similar dependent claim under another independent claim, the intent is that any direct comments made apply equally to the similarly worded dependent claim appearing under other independent claims.

Prosecution of a patent application before the Patent and Trademark Office is and should be a cooperative venture. The Office desires to crystallize the issues in this application and close prosecution at least by the next Office action. While it is recognized that applicant is entitled to claim that which he regards as his invention and to present a reasonable number of claims in his attempt to do so, it is suggested that it would be in the best interest of all parties concerned for applicant to reduce the number of claims in this application to a reasonable number. At least, applicant is urged to group the claims, much like the procedure in an appeal brief, so that effort can be concentrated on the essential issues and time not spent on dealing with ancillary features. In addition it is suggested that applicant cancel all claims currently pending and present those claims he wishes to pursue as newly renumbered claims, beginning with claim number 173.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David O. Reip at (703) 308-3383. The examiner can normally be reached Mon-Thu and every other Fri from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano, can be reached at (703) 308-2496. The fax number for this Unit is (703) 308-2708 (unofficial) or (703) 872-9302 (official). The examiner can also receive direct-to-computer faxes at 703-746-3310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at (703) 308-0858.

David O. Reip
Primary Examiner
April 19, 2002